



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,899	03/31/2004	John Riley Hawkins	101896-662 (DEP5055USNP)	1803
21125 7590 03/06/2009 NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			EXAMINER GANESAN, SUBA	
			ART UNIT 3774	PAPER NUMBER
			NOTIFICATION DATE 03/06/2009	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

Office Action Summary	Application No. 10/813,899	Applicant(s) HAWKINS ET AL.	
	Examiner SUBA GANESAN	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-10 and 12-66 is/are pending in the application.
4a) Of the above claim(s) 14-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6,7,9,10,12,13,54-61 and 63-66 is/are rejected.
- 7) ☒ Claim(s) 8 and 62 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, see remarks, filed 11/25/2008, with respect to the rejection(s) of claim(s) 1,2,6,7,9 and 10 under 35 USC 102(b) have been fully considered and are persuasive. The Michelson midline marker appears to not embed in the face of the vertebral body. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Michelson in combination with Manglardi et al. (U.S. Pat. No.: 5,665,092).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-4, 6-7, 9-10, 56-61, and 63-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson (U.S. Pat. No.: 6,224,607) in view of Manglardi et al. (U.S. Pat. No.: 5,665,092).

4. Michelson discloses an anterior method (col. 9 line 25) for implanting an artificial disc (implants, for example fig. 29) comprising:

- (a) fixing a position of a midline marker 118 to mark a midline thereof,
- (b) inserting a distraction instrument (fig. 5) into the intervertebral space using the midline marker as a guide (via reference marks 118)
- (c) selecting an artificial disc for implantation (fig. 29, for example); and

(d) inserting the artificial disc using the midline marker as a guide (fig. 29, for example).

5. Michelson relies on reference marks 118 on the face of a vertebral body to mark the midline of the spine. Michelson fails to show a midline marker that embeds in the face of a vertebral body. Manglardi teaches the use of a spinal marker 3 that embeds in the face of bone resulting in a surgical marker that accurately marks the location of a desired surgical procedure, including providing the surgeon with a reliable indication of the location and angle of the intervention on the bone surface (See abstract and col. 2 lines 16-24).

6. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the midline marker disclosed by Michelson with a marker that embeds in the face of a vertebral body as taught by Manglardi to accurately mark the location and angle of the surgical site of Michelson. Such a modification of the surgical method of Michelson would have been an obvious modification considering the advantages of the Manglardi marker, including increased accuracy. The modification would have occurred using known methods and yielding predictable results.

The implant of Michelson is considered to be an artificial disc because it replaces the native disc. A window is removed from the annulus (see fig. 27-29). The disc is fitted with trial spacers 291 (see fig. 30 and related description of spacer 291). It is considered inherent that the nucleus pulposus would be removed to create such a space. The endplates are shaped via a bone compactor 240, which is guided by the midline marker (via reference marks 118) and includes shaping blades 244.

Art Unit: 3774

7. With respect to claims 3-4, 56-61, Michelson discloses a radiopaque pin 104 used to verify the disc space. However, this pin is located on the midline marker instrument 100. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have included the pin on a verification instrument separate from the midline marker, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177,179.

8. Claims 12-13, 54-55, and 65-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson (U.S. Pat. No.: 6,224,607) in view of Manglardi et al. (U.S. Pat. No.: 5,665,092), as applied above, and further in view of Nolan (U.S. Pat. No.: 6,117,174).

9. Michelson in view of Manglardi is explained supra. However, Michelson and Manglardi lack implanting an artificial disc with endplates, a core and a retention clip. Nolan teaches the use of an implant 10 with endplates 18, 20, a core 14 and a retention clip C resulting in a prosthesis that is easier to install and has improved integrity. It would have been obvious to one of ordinary skill in the art to have modified the methods of Michelson and Manglardi to include the implant of Nolan for the purpose of providing an implant that is easier to install and has better implant integrity.

Allowable Subject Matter

10. Claims 8 and 62 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUBA GANESAN whose telephone number is (571)272-3243. The examiner can normally be reached on M-F 7-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3774

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. G./
Examiner, Art Unit 3774

/DAVID ISABELLA/
Supervisory Patent Examiner, Art Unit 3774